

THAT WHICH IS CLAIMED:

1. A composition comprising:
(a) an insulin-like growth factor-1 (IGF-I) or an IGF-I analogue,
5 wherein the IGF-I or IGF-I analogue is soluble in said composition at a concentration
of at least about 12 mg/ml when said composition is at a temperature of about 4°C;
and
(b) a solubilizing compound comprising a guanidinium group;
wherein said composition has a pH of at least about pH 5.5.
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2. The composition of claim 1, wherein said solubilizing compound is
arginine or an arginine analogue.
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3. The composition of claim 1, wherein said solubilizing compound is
guanidine hydrochloride.
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4. The composition of claim 1, wherein said solubilizing compound is
present in a molar concentration range from about 10 mM to about 1 M.
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5. The composition of claim 1, wherein said solubilizing compound is
present in a molar concentration range from about 15 mM to about 500 mM.
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6. The composition of claim 1, wherein said solubilizing compound is
present in a molar concentration range from about 20 mM to about 200 mM.
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7. The composition of claim 1, wherein said pH is in a range from about
pH 5.5 to about pH 9.0.
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8. The composition of claim 1, wherein said pH is in a range from about
pH 5.7 to about pH 6.3.
- 45
9. The composition of claim 1, wherein said pH is about pH 6.0.

10. The composition of claim 1, wherein said IGF-I or IGF-I analogue is present in said composition in a concentration of about 12 mg/ml to about 200 mg/ml.

5 11. The composition of claim 1, wherein said IGF-I or IGF-I analogue is present in said composition in a concentration of about 15 mg/ml to about 200 mg/ml.

12. The composition of claim 1, wherein said IGF-I or IGF-I analogue is present in said composition in a concentration of about 25 mg/ml to about 200 mg/ml.

10 13. The composition of claim 12, wherein said composition comprises sodium chloride at a molar concentration of about 150 mM.

14. The composition of claim 1 comprising a buffer selected from the group consisting of a glutaric acid buffer, a maleic acid buffer, a succinic acid buffer, 15 a citric acid buffer, imidazole, and a histidine buffer.

15. A composition comprising:
(a) an insulin-like growth factor-1 (IGF-I) or an IGF-I analogue, 20 wherein the IGF-I or IGF-I analogue is soluble in said composition at a concentration of at least about 12 mg/ml when said composition is at a temperature of about 4°C;
(b) a solubilizing compound selected from the group consisting of arginine, an arginine analogue, and guanidine hydrochloride; and
(c) a buffer such that the composition has a pH of about pH 5.5 to about pH 9.0.

25 16. The composition of claim 15, further comprising sodium chloride at a molar concentration of about 150 mM.

30 17. A method of making an IGF-I composition comprising:
(a) providing an amount of an insulin-like growth factor-1 (IGF-I) or an IGF-I analogue such that the IGF-I or IGF-I analogue is soluble in said composition at a concentration of at least about 12 mg/ml when said composition is at a temperature of about 4°C; and

(b) combining the IGF-I or IGF-I analogue with a solubilizing compound comprising a guanidinium group; wherein the pH of the composition is about pH 5.5 to about pH 9.0.

- 5 18. A method of delivering IGF-I to a vertebrate subject comprising:
- (a) providing a composition according to claim 1; and
- (b) administering said IGF-I composition to said vertebrate subject.
- 10 19. The method of claim 18, wherein the administering is parenteral.
- 15 20. A method of enhancing the solubility of an insulin-like growth factor-1 (IGF-I) or an IGF-I analogue in a composition having a pH of about pH 5.5 to about 9.0, said method comprising combining IGF-I or an IGF-I analogue with an amount of a solubilizing compound that comprises a guanidinium group sufficient to increase the solubility of IGF-I or the IGF-I analogue relative to the solubility of IGF-I or the IGF-I analogue in the absence of the solubilizing compound.

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